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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,816	10/02/2006	**Bruce Reidenberg**	208.1010US	3960

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Davidson, Davidson & Kappel, LLC
485 7th Avenue
14th Floor
New York, NY 10018

EXAMINER	
ORWIG, KEVIN S	
ART UNIT	**PAPER NUMBER**
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,816	REIDENBERG ET AL.	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,18,19,21-23,31,32 and 37-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,18,19,21-23,31,32 and 37-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendments and arguments filed Nov. 24, 2010 are acknowledged and have been fully considered. Claims 1-13, 18, 19, 21-23, 31, 32, and 37-40 are now pending and are now under consideration. Claims 14-17, 20, 24-30, and 33-36 are cancelled; claims 1, 3, 5, 7, 8, 12, 13, 22, and 23 are amended; claims 37-40 have been added.

OBJECTIONS/REJECTIONS WITHDRAWN

The rejection of claims 1-13, 18, 19, 21-23, 31, and 32 under 35 U.S.C. 112, 2nd paragraph is withdrawn in light of the claim amendments.

The rejection of claims 1, 5, 8, 12, 13, 18, and 21 under 35 U.S.C. 102(b) over GRANGER is withdrawn in light of the claim amendments.

The rejection of claims 2-4, 6, 7, 9-11, 19, 22, 23, 31, and 32 under 35 U.S.C. 103(a) over GRANGER and GALE is withdrawn in light of the claim amendments.

The double patenting rejections of record have been withdrawn in favor of the new double patenting rejection presented below.

OBJECTIONS/REJECTIONS MAINTAINED

The objection to the abstract is maintained as discussed below for the reasons of record.

Specification Objections (Maintained)

The abstract of the disclosure is objected to because the abstract is not adequately descriptive. The current abstract is essentially a one-sentence restatement of the title of the

application. 37 CFR 1.72(b) states that: "...The purpose of the abstract is to enable the United States Patent and Trademark Office and the public generally to determine quickly from a cursory inspection the nature and gist of the technical disclosure." No additional information is currently provided in the abstract that one could not obtain from the title of the application. A new abstract (150 words or less) is required that is sufficiently detailed as to provide general information about the precise nature of the invention to which the claims are directed. New matter is not permitted in the revised abstract. Correction is required. See MPEP § 608.01(b).

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that they have provided a new abstract (response, p. 11).

The new abstract fails to address the issue raised previously regarding the brevity and lack of detail in the abstract. The new abstract is still essentially a one-sentence restatement of the title of the application, and is inadequately descriptive. A new abstract should be provided that includes more detail than is currently present. Expanding the abstract past its current one-sentence format would be helpful.

NEW GROUNDS OF OBJECTION/REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 5-13, 18, 19, 21-23, 31, 32, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over GRANGER (U.S. 5,149,538; Issued Sep. 22, 1992; on 12/26/06 IDS) in view of SACKLER (U.S. 2003/0068392; Pub. Apr. 10, 2003) and McGINITY (U.S. 5,288,502; Issued Feb. 22, 1994).

1. Granger discloses misuse-resistive transdermal opioid dosage forms for analgesic effect (title; abstract; col. 2, lines 29-33) that are highly similar to those instantly claimed. For example, Fig. 3 of Granger illustrates an embodiment wherein an opioid antagonist is encapsulated and dispersed within a medium (i.e. a matrix) containing the opioid drug (Fig. 3; col. 6, lines 13-19). In particular, Granger teaches that the antagonist particles may be microencapsulated (claim 1, element d). Note the definition of "microsphere" in the instant specification (par. [0032]) encompasses a variety of particles. Granger further recognizes the

benefit of making the antagonist difficult to separate from the agonist (Fig. 3; col. 1, lines 55-59; col. 2, lines 12-13; col. 6, lines 11-13; col. 7, lines 53-56). Naltrexone is the preferred antagonist (col. 2, lines 65-68). Thus, Granger discloses the patches (*and inventive concept*) of the claimed invention. Granger is substantially structurally identical to the patches instantly claimed, except for the teaching of a microemulsion in the antagonist particles, which Granger does not teach. Besides teaching that the antagonist is encapsulated by a barrier means (col. 6, line 58 to col. 7, line 11), Granger does not elaborate on the internal structure of the antagonist particles. Thus, the ordinary artisan would have reason to look to the literature for guidance as to the composition of the antagonist particles.

2. Similar to Granger, Sackler discloses transdermal devices intended to address the problem of misuse of transdermal pharmaceutical devices (title; abstract; pars. [0183]-[0190]). Sackler specifically refers to Granger in par. [0190], stating:

> "The aversive agent and antagonist in non-releasable form when administered intact can be formulated in accordance with U.S. Pat. No. 5,149,538 to Granger, hereby incorporated by reference." (par. [0190])

3. Moreover, under the heading "PREPARATION OF AVERSIVE AGENT IN A SUBSTANTIALLY NON-RELEASABLE FORM" Sackler teaches:

> "In certain embodiments of the present invention, an aversive agent in a substantially non-releasable form may be prepared by combining the aversive agent with one or more of a pharmaceutically acceptable hydrophobic material. For example, aversive agent particles may be coated with coating that substantially prevents the release of the aversive agent, the coating comprising the hydrophobic materials(s). Another example would be an aversive agent that is dispersed in a matrix that renders the aversive agent substantially non-releasable, the matrix comprising the hydrophobic materials(s) ... In certain other embodiments, the hydrophobic material comprises polylactic acid, polyglycoilc acid or a co-polymer of the polylactic and polyglycolic acid." (par. [0088], emphasis added)

> Additionally, Sackler teaches:

> "The pharmaceutically acceptable hydrophobic material useful for preparing an aversive agent in a substantially non-releasable form includes a biodegradable polymer comprising a poly(lactic/glycolic acid) ("PLGA"), a polylactide, a polyglycolide, a polyanhydride, a polyorthoester, polycaprolactones, polyphosphazenes, polysaccharides, proteinaceous polymers, polyesthers, polydioxanone, polygluconate, polylactic-acid-

> polyethylene oxide copolymers, poly(hydroxybutyrate), polyphosphoesther or mixtures or blends of any of these." (par. [0096], emphasis added)

4. Sackler also specifies that the biodegradable polymer can be poly(lactic/glycolic acid), a copolymer of lactic and glycolic acid (par. [0097]).

5. Moreover, McGinity discloses multi-phase microspheres containing a microemulsion and methods for preparing the same (title; abstract; col. 4, lines 34-45 and 61 to col. 5, line 14 and col. 5, lines 34-37). McGinity teaches that drug compounds are effectively trapped within multiple tiny oil droplet reservoirs throughout a polymer matrix (col. 5, lines 15-25). McGinity teaches that the multi-phase microspheres of the present invention include a polymeric substance such as poly (D,L-lactic acid) and poly (D,L-lactic) co-glycolic lactic acid, which are the most preferred polymers to be used in conjunction with the disclosed multi-phase microspheres (col. 6, lines 59-64). McGinity teaches that the multi-phase microspheres are most preferably about 150 μm in size, even more preferably between 50 μm and 100 μm in size (col. 6, lines 48-51). McGinity teaches that high efficiency in drug loading (preferably more than 90%) is a required feature in clinically efficacious microencapsulation techniques, and teaches that drug loading capacity loading efficiency, stability and controlled release have been observed as limiting factors even when highly potent water soluble drugs are incorporated into microparticles (col. 3, lines 22-31). A microcapsule delivery system which permitted the efficient loading of water-soluble biologically active molecules in a biodegradable carrier system would provide a medically significant advance in the clinically valuable and cost-effective preparations for long-term in vivo drug delivery of potent water-soluble chemicals (col. 3, lines 54-59). Thus, McGinity's disclosure addresses these problems, by providing multi-phase, microemulsified microspheres that are advantageous since they allow for high drug loading efficiencies and improved drug stability over prior art microparticles (abstract; col. 1, line 67 to col. 2, line 12; col. 3, lines 17-25 and 63-65). McGinity teaches that the inventive multi-phase microspheres may

be used with virtually any micro- or macromolecule to provide a highly cost effective delivery system (col. 5, lines 46-52).

6. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to formulate the encapsulated particles of opioid antagonist disclosed by Granger using PLGA copolymers as taught by Sackler and McGinity, specifically using the multi-phase microemulsified microspheres taught by McGinity. One would have been motivated to do so since these polymers are taught as the most preferred polymers for substantially the same use (see Sackler), and since McGinity teaches that using such multi-phase microspheres allows improved drug loading, drug stability, and cost effectiveness. Doing so amounts to no more than combining prior art elements according to known methods to yield predictable results. The combination of Granger, Sackler, and McGinity renders obvious claims 1, 2, 5, 6, 11-13, 18, 19, 21-23, 31, and 32.

7. Regarding claims 5 and 21, Granger teaches that the opioid drug is dispersed in a polymeric matrix (delivery means) (col. 3, line 48 to col. 4, line 20).

8. Regarding claims 7 and 8, the MPEP states that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). "A consisting essentially of' claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355. Furthermore, the MPEP states that if an applicant contends

that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

9. Regarding claims 9 and 10, Granger teaches microencapsulated particles, which any skilled artisan would understand as referring to particles in the micron size range (e.g. on the order of from 0.1-1000 microns). Further, the instant claims all use the term "about" in reference to the claimed diameter ranges. It is noted that the term "about" is not defined or discussed in the instant specification, and thus is given significant leeway. Additionally, McGinity teaches that the multi-phase microspheres are most preferably about 150 μm in size (col. 6, lines 48-49). Thus the teachings of the prior art are also given leeway and the prior art teaching of about 150 μm renders obvious the claimed ranges starting at about 200 μm or about 300 μm. This is particularly true since the MPEP states that a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). See MPEP § 2144.05(I). It is further noted that ranges of 1-500 μm are claimed throughout the instant claims, in various range increments. Thus, the particular size ranges in any given claim do not appear to be critical to the essential function of the invention, and particles within any of these sizes all appear to be interchangeable alternatives, absent evidence to the contrary. Claims 9 and 10 are obvious over Granger, Sackler, and McGinity.

10. Regarding claims 22 and 23, Granger teaches that the opioid matrix delivery means can comprise materials such as, *inter alia*, silicone elastomers and silicone copolymers (elected species) (col. 3, lines 52-64).

11. Regarding claims 39 and 40, Sackler establishes the functional equivalence of poly(lactic/glycolic acid) ("PLGA"), polylactides, polyglycolides, polyorthoesters, polycaprolactones, and mixtures or blends of any of these (par. [0096]). In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use any of the polymers discussed by Sackler, particularly as a copolymer with the preferred polymers (i.e. PLA and PGA) taught by McGinity. It must be remembered that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR v. Teleflex*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. A.G. Pro*, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (*Id.*). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR v. Teleflex*, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." *Id.* at 1742. Consistent with this reasoning, it would have been obvious to have selected various combinations of the polymers taught by Sackler, particularly since Sackler suggests such combinations for the very same use suggested by Granger (and claimed by applicants), "yielding no more than one would expect from such an arrangement." The combination of Granger, Sackler, and McGinity renders obvious claims 39 and 40 obvious.

Response to Arguments

While applicants' arguments are largely moot in light of the new rejections applied herein, certain aspects of applicants' arguments are addressed insofar as they may apply to the new rejections. Applicants argue that the instantly claimed transdermal device is "structurally distinct" from the transdermal devices of Granger (response, p. 12).

Applicants assert that the antagonist of Granger's device is not "releasable from the transdermal device administered intraoraly". Applicants' argument hinges on the explicit language used by Granger, ignores the spirit of Granger's invention, and more importantly ignores the fact that there is no structural difference that would prevent Granger's devices from releasing the antagonist intraorally (i.e. within the mouth). Indeed, applicants have failed to point to a single structural feature that would impart such a difference in behavior between Granger and the claimed patches. Applicants are invited to point to the description of such a feature in Granger by column and line number, or in the instant claims. Par. [0024] of the published application states:

> "In a further embodiment, in the setting of intraoral abuse of a transdermal dosage form, saliva would penetrate the transdermal formulation and dissolve the microspheres, releasing the antagonist and decreasing the value of the transdermal formulation to the abuser." (par. [0024])

What is different about applicants' claimed transdermal device that would allow saliva to penetrate it and not the devices of Granger? Applicants do not say. Applicants' quotations from Granger are correct (e.g. response, p. 12). Granger does not explicitly use the word "intraoral". However, does that mean that Granger's devices are incapable of releasing the antagonist in the oral cavity, such as when the transdermal patch is sucked by a drug abuser? In the absence of a credible structural feature that would preclude this release, the answer is clearly in the negative. It is further noted that Granger teaches that the opioid antagonist is released from the dosage form upon being ingested or substantially immersed in water or other solvents. Ingestion reasonably reads on "intraoral", and there is not clear indication of what "substantially

immersed" means, despite applicants' implication to the contrary. When an item is placed in the oral cavity, this generally stimulates the mouth to salivate, thus covering the item with saliva. The examiner requests that applicants explain how intraoral administration does not constitute "substantial immersion" in an aqueous liquid (e.g. saliva).

Applicants are missing the point of Granger's disclosure, that *any* behavior or environment that results in aqueous fluids (or other solvents such as alcohol) penetrating into the substantially anhydrous matrix containing the antagonist particles will result in the release of the antagonist. Applicants have done nothing more than describe the antagonist release scenarios in more detail than Granger did. Granger's failure to describe the antagonist release scenarios in more detail can be attributed to the fact that there are myriad ways in which drug abusers can attempt to remove an opioid drug from a transdermal patch, and an inventor cannot possibly be expected to list all (or even most) of them. But that lack of detail is in no way evidence that the devices could not release the antagonist in the scenarios that are not described. *In the absence of any structural feature or evidence* to support the assertion that Granger is incapable of release in the oral cavity, applicants' arguments are unpersuasive. As further evidence of what other artisans in the field have understood Granger to mean, applicants are pointed to VAN DUREN (U.S. 2004/0191301). Van Duren actually refers to and briefly discusses Granger at par. [0008], and states:

> "One method to combat such abuse is disclosed in U.S. Pat. No. 5,149,538 in which an analgesic antagonist is added to a transdermal patch containing an analgesic drug. Initially, the antagonist is separated from the analgesic drug by a barrier that is soluble in water, alcohol or an organic solvent. In use, if the transdermal patch is immersed in water, the barrier dissolves, releasing the antagonist to mix with, and neutralize, the analgesic drug. One disadvantage of this design is the soluble barrier, which may release the antagonist prematurely if the patch gets wetted accidentally, or is disposed in a humid environment, such as when a user showers or bathes." (par. [0008], emphasis added)

Clearly, "accidental wetting" or "disposition in a humid environment" do not fall into the category of total immersion, but were understood by Van Duren to be situations in which the

antagonist of Granger would be released, contrary to applicants' unsupported assertion. Granger's transdermal devices, which are structurally identical to those instantly claimed (except for the microemulsion) would be capable of releasing the antagonist intraorally, absent evidence to the contrary.

Claims 3, 4, 37, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Granger, Sackler, and McGinity as applied to claims 1, 2, 5-13, 18, 19, 21-23, 31, 32, 39, and 40 above, and further in view of RAVIVARAPU (Ravivarapu, H. B., *et al.* Pharm. Dev. Tech. (2000), 5(2); 287-296).

12. The teachings of Granger, Sackler, and McGinity are presented *supra*. The references teach all of the other limitations of the claims (discussed *supra*), but do not teach the use of calcium chloride. However, including calcium chloride in the microparticles would have been obvious to a skilled artisan at the time of the invention.

13. For example, Ravivarapu reports on the factors affecting the release of drugs from PLGA microspheres (title; abstract). Ravivarapu teaches that calcium chloride is a porosigen that can increase the porosity of the PLGA microspheres (abstract; p. 228, top of 2nd col.). Ravivarapu teaches that the initial rate of release of drug in PLGA microspheres can be adjusted by using calcium chloride (p. 295, top of 1st col.).

14. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include calcium chloride in the microspheres taught by McGinity to control the initaial rate of release of the antagonist from the microspheres. For example, an artisan might wish to have a high initial burst of drug release from the microspheres to provide a strong deterent to drug abuse of the transdermal devices. The combination of Granger, Sackler, McGinity, and Ravivarapu renders obvious claims 3, 4, 37, and 38.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

U.S. Patent Application No. 11/865,387

Claims 1-13, 18, 19, 21-23, 31, 32, and 37-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 11/865,387 in view of Granger, Sackler, McGinity, and Ravivarapu. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the '387 claims anticipates or renders obvious that of the instant claims. The difference between the two claim sets is that the instant claims recite certain polymer materials and antagonist particle sizes. However, these elements, and thus the entire scope of the instant claims, are rendered obvious by Granger, Sackler, and McGinity, as discussed above. Furthermore, selection of the appropriate form(s) of a drug is within the purview of the skilled artisan. It is further noted that at least some amount of free-base and/or salt form will be present in a reservoir having a majority of the other form of the drug, specifically when water penetrates the reservoir to release the antagonist (i.e. the adverse agent). Moreover, Granger teaches the claimed forms.

Summary/Conclusion

Claims 1-13, 18, 19, 21-23, 31, 32, and 37-40 are rejected; claims 14-17, 20, 24-30, and 33-36 are cancelled.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KSO/

/Allison M. Ford/
Primary Examiner
Art Unit 1651